REMARKS

The claims

Claim 1 has been amended to recite, *i.a.*, that a steroidal preparation "consisting essentially of" gestagen is administered during (a). The recitation of "consisting essentially of" excludes administering other agents during (a) in amounts that would affect the basic and novel characteristics of Applicants' claimed invention. See, e.g. *In re Garnero*, 162 USPQ 221 (CCPA 1969).

Newly added claims 13-30 recite further aspects of the invention and are fully supported in the specification.

For example, new claim 13, recites that estrogen is administered in (b) in an amount effective for achieving regular menstrual-like bleeding, during only 5 to 10 days at the end of the at least 28 day period. This subject matter is supported in the specification at, *e.g.*, page 5, line 22 to page 6, line 9.

Newly added claims 26-30 are supported by, for example, the recitations of original claims 8-12.

The restriction requirement

The requirement for restriction of "kit" claims 8-12 is traversed, on the grounds that the examination of the kit claims would not amount to a serious burden upon the PTO. (It appears that claim 8 should have been included in Group II.) The kit claims of Group II recite the reagents which are used to implement embodiments of the method claims of Group I. As a result, the search for Group I necessarily encompassed the search required for Group II. Thus, the subject matter of the non-elected claims has already been searched. In the absence of a serious burden on examination, restriction is not proper. See MPEP § 803. Furthermore, the claimed kit and methods of using the elements of the kits certainly have unity of invention. Thus, withdrawal of the restriction requirement is respectfully requested.

Rejections under 35 USC 102 and 103

Neither Gast ('480) nor Koninckx ('843), taken individually or together, anticipates or renders obvious the instant invention.

Gast discloses a method in which, first, a progestin/estrogen combination is administered; then, immediately following the last day of administration of the combination,

estrogen *alone* is administered (see, *e.g.*, col. 10, lines 55-70 of the reference). The reference clearly does not disclose or suggest all the elements of the claimed invention, *e.g.*, that estrogen and gestagen are both administered during 5-10 days at the end of the at least 28 day period. Therefore, the reference does not anticipate the claimed invention. "An anticipation rejection requires a showing that each limitation of a claim must be found in a single reference, practice or device." (*In re Donohue*, 226 USPQ 619 (CAFC 1985))

Koninckx discloses a contraceptive method in which estrogen doses oscillate such that "estrogen-dominant" and "progestogen-dominant" periods occur alternatingly, with a periodicity which is effective for optimal cycle control (see, *e.g.*, col. 1 line 67 to col. 2, lines 1-4; col. 1, lines 50-52; and examples 4 and 5). In disclosing that "the estrogen dose oscillates between two levels" (see, *e.g.*, col. 2, lines 27-29), Koninckx clearly suggests administering estrogen in pharmacologically effective amounts (*e.g.*, amounts effective for optimal cycle control) *throughout* the entire administration period; one of ordinary skill in the art would interpret the specification in this fashion. See also Examples 1-7 of Koninckx, which show administration of estrogen throughout the cycle. Examples 4 and 5 are said to use estrogen doses which are "as low as possible". Koninckx fails to disclose or suggest a period of administration during which a steroidal preparation consisting essentially of a gestagen is administered (compare instant claim 1), or a period of administration during which estrogen is not administered in an amount effective for achieving regular menstrual-like bleeding (compare instant claims 13 and 14). Furthermore, Koninckx does not disclose or suggest a gestagen-dominant period which extends for as long as 18 or more days. If anything, Koninckx discloses that, preferably, each of the gestagen-dominant or estrogen-dominant phases has a duration of less than 10 days, more preferably less than 7 days, or between 2-6 days (see, *e.g.*, Abstract and col. 2, lines 20-22). Koninckx does not even disclose that the progestogen-dominant phase is in the first part of the administration period. Compare Applicant's claim 14. Because Koninckx fails to disclose all of the elements of the claimed method, it is not anticipatory. *(Donohue, supra)*

Furthermore, Gast and Koninckx, taken either individually or together, do not render the instant claims obvious. Neither Gast nor Koninckx suggests or discloses modifying their methods in the ways required in order to achieve the claimed methods. Many contraceptive methods have been proposed which employ various combinations of gestagens and estrogen, including the methods cited in this office action; but the mere fact that such agents have been

used in combination does not motivate one to use them in the particular combination and order recited in Applicants' claims. "Obvious to try" does not constitute adequate motivation. Absent motivation, with the requisite reasonable expectation of success, to modify the methods disclosed by Gast and/or Koninckx so as to achieve the combinations of agents and order of administration recited in the instant claims, the references do not render obvious the claimed invention. *In re Vaeck*, 20 USPQ2d 1438 (Fed. Cir. 1991).

The Neuman abstract also fails to render obvious the claimed invention. The abstract summarizes a review article which apparently discloses several forms of estrogen-progestagen drug combinations for contraception. However, the Examiner has not pointed to any disclosure in this abstract of a method comprising the particular agents and order of administration recited in the instant claims. As noted above, the mere disclosure of contraceptive methods employing combinations of estrogen and progestagen in no way provides motivation, with the requisite reasonable expectation of success, to modify the disclosure so as to arrive at the instant claims. Neuman therefore does not render obvious the claimed invention.

The Examiner is requested to consider and initial the references listed in the IDS filed December 3, 1999.

In view of the above amendments and remarks, this application is believed to be in condition for allowance, which action is respectfully requested.

Respectfully submitted,

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